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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,305	09/10/1999	KEIYA OZAWA	50026/012001	2019

21559 7590 03/12/2007

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/142,305	OZAWA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18,21 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,18,21 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05, 3/06, 8/06, 1/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 08 January 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 18, 21, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107

> F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

4. A review of the application papers finds that no computer-readable Sequence Listing has been filed in the instant application.

5. A review of the disclosure finds the following six examples:

- Example 1, page 9, "Constructing the chimeric G-CSF receptor/estrogen receptor gene (a selective amplification gene).
- Example 2, pages 9-11, "Isolation of Ba/F3 cells into which was introduced the chimeric G-CSF receptor/estrogen receptor gene, which is a selective amplification gene."
- Example 3, page 11, "Analysis of cell proliferation by estradiol."
- Example 4, pages 11-12, "Construction of IRES-CD24 expression plasmid."
- Example 5, pages 12-13, "Intracellular expression of CD24."
- Example 6, pages 13-15, "Progenitor assays.'

6. The specification has not been found to provide an adequate written description of any amino acid sequence that is associated with any of the stipulated functions or activities of the various components.

7. It is noted with particularity that the invention of claims 1, 18, 21, and 24 is that of fusion proteins, a product, and not to methods for their production. Claim 1 identifies a first and second polypeptide. The first polypeptide "comprising an estrogen-binding receptor domain of a human

estrogen receptor," and the second polypeptide "comprises a human or murine granulocyte colony stimulating factor receptor." It is noted with particularity that the first and second polypeptides are not limited to any specific sequence, but fairly encompass derivatives of any "human" or "murine" polypeptide that has the requisite properties. The specification does not identify what amino acid sequences are associated with the properties, nor does the specification teach how and to what degree the amino acid sequence be modified, substituted and/or deleted and the requisite properties still be retained. Example 14 of the Written Description Guidelines shows that there needs to be a recitation of structure (SEQ ID NO.) and function, and then the degree of variability from what is disclosed, yet still meeting the test of written description is limited to like molecules that have 95% or greater identical sequences. While reference has been made to a "wild type murine granulocyte colony stimulating factor receptor," there is no showing in the specification as to just what the "wild type" sequence is. And as noted above, the specification does not teach where and how any of the requisite polypeptides can be modified and still retain functionality.

8. None of the examples teach that any fusion protein has been produced and isolated and subsequently found to have the requisite activity, yet such embodiments are encompassed by the claims.

9. The specification does not provide sufficient description for a representative number of structural properties coupled with a known or disclosed structure to function correlation. The specification provides an example of Ba/F3 or murine mononuclear cells transformed with three variants of one type of cytokine receptor proliferation domain (i.e., murine G-CSF receptor). More particularly, two relevant fusion constructs are disclosed comprising a chimeric G-CSF

receptor/estrogen ligand binding domain construct - "GCRER" as well as a construct with portions deleted in the G-CSFR extracellular domain from the 5th to the 195th residue - GCRΔ (5-195)/ER. (e.g., p. 9, Example 1). Therefore, GCRA (5-195)/ER and GCRER are the only relevant embodiments that are disclosed.

10. In sum, two embodiments of a cytokine receptor are disclosed and one embodiment for a hormone ligand-binding domain (HBD), linked to either the wild type G-CSFR or GCRΔ (5-195).

11. The knowledge in the art does not provide sufficient relevant information to fill the gap present in the instant disclosure. For example, there are a few examples of particular fusion molecules consisting of a cytokine receptor and a hormone ligand-binding domain, whereby the fusion protein imparts cell proliferation. (e.g., Capon et al. US 5,837,544,. teach a chimeric constructs encoding a ligand-binding domain or an inducer-responsive clustering domain (ICD) linked to a proliferation signaling domain (PSD); Nakabeppu et al., Mol. Cell. Biol. 1993, 13:4157-66, teach a fusion protein comprising the *FosB* cytokine receptor domain linked to the human estrogen receptor ligand binding domain, whereby *FosB* regulated proliferation of quiescent cells). However, a handful of examples do not suffice to describe the genus of fusion molecule structures encompassed by the claims, wherein said structures correlate to cell proliferation.

12. The fusion molecule components (i.e., cytokine receptor domains and hormone ligand binding domains) are the essential element of the invention, but are not shown to be necessarily interchangeable so that any combination will not necessarily result in the required functionality of imparting cell proliferation. Such fusion constructs are not deemed to be "conventional" in the

art, in the context of cell proliferation. (Supra, Guidelines, discussing critical or essential features of a claimed genus and the relative need for description when a feature is conventional in the art.)

13. While the claims are drawn to a fusion protein and not to a retroviral vector that comprises the coding sequence for the fusion protein, the claims have been interpreted as encompassing the fusion protein that is encoded by such a retroviral construct, and which has been introduced into a patient. Support for this interpretation is based in part on page 10 of the specification that teaches use of a retroviral vector so to introduce the fusion protein into certain cell types.

14. It is noted that issues of enablement are found in some 6 years post filing in the FDA's "Notification of a Serious Adverse Event" (actually two serious adverse events). As seen in the Notification, a fusion protein had been administered to human patients, with the fusion protein comprising a gene for the receptor of a cytokine and wherein a retroviral vector was used to introduce the fusion protein into the cell. The instant invention fairly comprises a fusion protein that also comprises a receptor for a cytokine as well as the use of a retrovirus of the introduction of the fusion protein into the target cells.

15. At page 1 of the "Notification," FDA Director states in part:

> **Moreover, the NIH is urging investigators conducting retroviral-mediated gene transfer in hematopoietic cells to discontinue enrollment and administration of experimental agent** until new data are available. (Emphasis in the original.)

16. A review of the application as filed fails to find where the claimed fusion protein has been found useful in any assay without it being introduced into a cell via retroviral vectors.

Further, post-filing communication fails to show that assertions of use have been realized using the claimed fusion proteins in accordance with disclosed methodologies.

17. In sum, given the enormous breadth of the genus of fusion molecules encompassed by the rejected claims, and given the limited description from the instant specification of such fusion molecules, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus. Moreover, an applicant claiming a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from other species (i.e., different combinations of receptors/binding domains comprising a given fusion molecule). Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the claimed invention.

18. Claims 1, 18, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute

> even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary,

The quantity of experimentation needed to practice the full scope of the invention is great- on the order of many man-years with little if any reasonable expectation of success.

The amount of direction or guidance presented,

The specification provides only prophetic guidance as to how the claimed fusion proteins are to be used.. Further, since the filing of the instant application, issues of safety and enablement have come to the forefront, *infra*.

The presence or absence of working examples,

A review of the disclosure finds the following six examples:

- Example 1, page 9, "Constructing the chimeric G-CSF receptor/estrogen receptor gene (a selective amplification gene).

- Example 2, pages 9-11, "Isolation of Ba/F3 cells into which was introduced the chimeric G-CSF receptor/estrogen receptor gene, which is a selective amplification gene."
- Example 3, page 11, "Analysis of cell proliferation by estradiol."
- Example 4, pages 11-12, "Construction of IRES-CD24 expression plasmid."
- Example 5, pages 12-13, "Intracellular expression of CD24."
- Example 6, pages 13-15, "Progenitor assays.'

The specification does not provide any Sequence Listing for any fusion protein and does not tie the requisite functional attributes to any particular structure. It is further noted that the amino acid sequence is subject to any degree of variation over that of any known sequence (applicant's undefined "wild type" sequence). Such embodiments are outside the bounds of the 95% identity the first and second polypeptides of said fusion protein must have in order to comply with the Written Description requirement; *supra*. In short, applicant has not provided the essential starting materials and reaction conditions under which the claimed product can be used.
In short, applicant has not set forth the reaction conditions and starting materials that are essential to practicing the full scope of the claimed invention. Without the disclosure of such essential elements as the reaction conditions and starting materials, the skilled artisan is forced to conduct trial-and-error experimentation. Such efforts do not constitute routine but rather, undue experimentation. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable

correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

*****

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

The nature of the invention and predictability of the art,

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

It is noted that issues of enablement are found in some 6 years post filing in the FDA's "Notification of a Serious Adverse Event" (actually two serious adverse events). As seen in the Notification, a fusion protein had been administered to human patients, with the fusion protein comprising a gene for the receptor of a cytokine and wherein a retroviral vector was used to introduce the fusion protein into the cell. The instant invention fairly comprises a fusion protein that also comprises a receptor for a cytokine as well as the use of a retrovirus of the introduction of the fusion protein into the target cells.

At page 1 of the "Notification," FDA Director states in part:

> **Moreover, the NIH is urging investigators conducting retroviral-mediated gene transfer in hematopoietic cells to discontinue enrollment and administration of experimental agent** until new data are available. (Emphasis in the original.)

A review of the application as filed fails to find where the claimed fusion protein has been found useful in any assay without it being introduced into a cell via retroviral vectors. Further, post-filing communication fails to show that assertions of use have been realized using the claimed fusion proteins in accordance with disclosed methodologies.

The breadth of the claims

It is noted with particularity that the invention of claims 1, 18, 21, and 24 is that of fusion proteins, a product, and not to methods for their production. Claim 1 identifies a first and second polypeptide. The first polypeptide "comprising an estrogen-binding receptor domain of a human estrogen receptor," and the second polypeptide "comprises a human or murine granulocyte colony stimulating factor receptor." It is noted with particularity that the first and second

polypeptides are not limited to any specific sequence, but fairly encompass derivatives of any "human" or "murine" polypeptide that has the requisite properties. The specification does not identify what amino acid sequences are associated with the properties, nor does the specification teach how and to what degree the amino acid sequence be modified, substituted and/or deleted and the requisite properties still be retained. Example 14 of the Written Description Guidelines shows that there needs to be a recitation of structure (SEQ ID NO.) and function, and then the degree of variability from what is disclosed, yet still meeting the test of written description is limited to like molecules that have 95% or greater identical sequences. While reference has been made to a "wild type murine granulocyte colony stimulating factor receptor," there is no showing in the specification as to just what the "wild type" sequence is. And as noted above, the specification does not teach where and how any of the requisite polypeptides can be modified and still retain functionality.

19. In view of the breadth of scope claimed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are not enabled by the disclosure.

20. The declaration under 37 CFR 1.132 filed 08 January 2007 is insufficient to overcome the rejection of claims based upon 35 USC 112, first paragraph, as set forth in the last Office action because: The claims are not limited to any specific sequence, or percent identity to any specific sequence to which a structure-function relationship has been established prior to the time of filing. While argument is raised at page 1 of the declaration that "G-CSF receptors are a class

of proteins that were extraordinarily well characterized at the time the application was filed," such well characterization does not equate with enabling its use. In support of this position, attention is again directed to the FDA's "Notification of Serious Adverse Event," which has advised that no further research be conducted in delivering a similar compound through the very means contemplated by applicant.

21. The showings by the two evidentiary documents fail to teach what is the "wild type" of any specific sequence. Rather, they provide a sequence of murine granulocyte colony-stimulating factor (G-CSF) that was isolated from "a CDM8 expression library of mouse myeloid leukemia NFS-60 cells" (Fukunaga et al., *Cell*, Vol. 61, 1990, pp. 341-350. and Larsen et al., J. *Exp. Med.*, Vol. 172, December 1990, 1559-1570.). There is no evidence that a determination had been made as to just what the murine "wild type" sequence was. Further, that fact that the sequence was isolated from a myeloid leukemia NFS-60 cell line in and of its self raises questions as to the potential for splice variants.

22. As noted above, the claims are not limited to any "wild type sequence," but rather, fairly encompass polypeptides where their amino acid sequence has undergone any number and form of derivation. Neither the specification, attorney argument, declarant, or supporting evidence has been found to provide a full, clear, concise, and exact description of just what these alternative sequences are, much less an enabling disclosure of how they are to be used.

23. Accordingly, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 12, first paragraph, is maintained.

24. Claims 1, 18, 21, and 24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

25. Claims 1, 18, 21, and 24 are all drawn to a fusion protein. The specification, at pages 4-6, discloses 17 aspects of the invention. While aspects 7 and 16 are directed to a method of selective proliferation of a cell, the methods require the use or presence of a vector. None of the disclosed embodiments of the invention are directed to the actual use of the claimed fusion protein absent a cell comprising a vector. The specification does not disclose where any specific, substantial, a credible use has been achieved by the selective proliferation of any cell in any organism. As noted above, the FDA has urged investigators to discontinue enrollment and administration of the "experimental agent until data are available." Such disclosure does not support a conclusion that utility existed in readily available form at the time of filing. Further, such statements by applicant, and by the FDA, speak to the continued study of such compounds for potential uses, or "use testing." Such testing does not satisfy the requirement for utility under 35 USC 101. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US Sup Ct 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating

> benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *
>
> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
>
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. (Emphasis added.)

26. For the above reasons, and in the absence to convincing evidence to the contrary, claims 1, 18, 21, and 24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

27. Claims 1, 18, 21, and 24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 571-272-0751. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS